

## HL7 SPL Working Group Process Communication Forum Telecon

Wednesday, April 08, 2009

Check out the SPL Working Group WIKI @:  
<http://spl-work-group.wikispaces.com>

### Meeting Minutes:

#### Drug Images in SPL

##### Product Image

The submission of the image of the solid oral dosage form drug product with an SPL document to FDA is not possible until FDA or NLM publishes a guidance document with the procedures for including a image of the drug product.

##### Principal Display Panel / Package Label

Image of the carton to be entered under PACKAGE LABEL.PRINCIPAL DISPLAY PANEL  
[LOINC Code 51945-4]

One company cross-references from this section to the 'How Supplied' section for a complete list of packages.

Q: Is it required? A representative sample of carton or container is required - See 21 CFR 207.25

Q: What specifically is required, e.g., collapsed carton? Several responses through different channels had the same answer: image of the collapsed carton, showing all panels, or a container label.

Q: What constitutes representative label: Several responses through different channels had the same answer: 1 carton or container

Q: What text should be captured? The intent is that text from the carton be searchable. From the principal display panel, capture whatever is there other than Drug Facts text (for OTC)?

For **OTC**: drug facts are included in content of label; anything else goes into the principal display panel. Open question: what exactly should the text be for OTC products?

For **Rx**: the text is what is included on the principal display panel only.

For **Vet** products – unknown at this time.

### **Still unanswered questions:**

Q: OTC products – Where will the SPL go to be available to the public after eList?

Q: Vet products - Where will the SPL go to be available to the public after eList?

Q: Facts @ FDA currently has everything – will this be the location for all SPL?

Q: Would ELIST file go from Facts @FDA to NLM

## 2 major technical issues in SPL r4 submissions

R4 files: SPL file(s) must be included in a folder. Otherwise, they will fail validation. The folder does not need to be named \SPL for R4 files in the eList process.

Incorrect gateway routing: Registration & Drug Listing Files should go through OC \ SPL ESG route. Application files for review should go through review division (CDER / CBER / CVM)

Q: Is the "spl" directory name case sensitive? -- This question was geared for SPL R4 submissions only.

A: The SPL directory naming convention is not required for SPL R4 files submitted for the purpose of electronic drug establishment registration and drug listing via the FDA Gateway. If it is submitted via the application process, the SPL directory name should be "spl." The name of the directory is case insensitive.

## Additional Training Session

Session Nine: Begins April 30 and extends through June 4

SPL Release 4 now approved as official ANSI standard

## Subteam Updates

### OTC Subteam

Planning for the next SPL workshop (sponsored by DIA, CHPA, etc.) – targeted for August 2009

### Generic Subteam

- Currently meeting approximately monthly, on Tuesdays at 1 PM (Eastern)

### Medical Devices Subteam

- Meeting scheduled for April 17. Overview of activities at HL7. Participation by Terrie Reed (CDRH)
- The group is fairly small. Anyone interested in joining/re-joining the Medical Device subteam, please contact Myron Finseth @ [myron.finseth@medtronic.com](mailto:myron.finseth@medtronic.com).

### ER/DL Subteam

- Submission of a product that is being discontinued - planned change in validation procedure. Include market stop date in SPL [Drug Listing]; no need to include Establishments in Drug Listing
- Export-only products – ongoing topic with lots of discussions. Some issues – do these need to have NDC codes? Foreign languages may be an issue for many software vendors.
- Additional issues? Raise them with this team – contact Michael.fahmy@bms.com.

### Biologics Subteam

- Letters still coming from FDA (CBER) to sponsors containing UNII codes and how they were determined
- Next meeting April 30, 2009

## Veterinary Medicine Subteam

- No updates

AOB:

*FDA is working on an OTC template now, and expects to release this in the near future.*

*UNII code list available at FDA now contains synonyms. You may find your ingredient in the synonym column, with a different preferred name next to the UNII code.*

**Next Meeting scheduled for Wednesday, April 22, 2009 from 1 – 2:30.**

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